K050651

MAY 16 2005

510(K) SUMMARY

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	31 December 2004
Device Name:	Armand Endoscope Holder
Trade Name:	Endoscope Holder
Common Name:	Endoscope Holder
Classification Name and Number:	Endoscope and/or accessories (CFR 876.1500)
Regulatory Class:	Class II
Predicate Devices:	Neuroview® Instrument Holder (Model 300-33) (K992006) KSEA Endoscope Holder (K990334)
Intended Use:	The Armand Endoscope Holder is intended for use by surgeons for holding rigid and flexible endoscopes with diameters from 14.6mm to 15.8mm during diagnostic and therapeutic procedures.
Device Description:	The Armand Endoscope Holder is a manually operated surgical device. It is composed of surgical grade stainless steel and anodized aluminum. The holder consists of a table clamp, adjustable stainless steel rods, and an endoscope clamp. The endoscope clamp is designed to hold endoscopes in diameter from 14.6mm to 15.8mm. The device uses a single knob clamp assembly to hold the endoscope and a single knob to tighten and lock the stainless steel rods into the desired position.

Technological Characteristics:

Similarities to Predicate

The Armand Endoscope Holder is similar in materials and description to the Neuroview ® Instrument Holder (Model 300-33) (K992006) and the KSEA Endoscope Holder (K990334)

Substantial Equivalence:

The Armand Endoscope Holder is substantially equivalent in application and function to the Neuroview ® Instrument Holder (Model 300-33) (K992006) and the KSEA Endoscope Holder (K990334).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2005

Ms. Jennifer Damato
Director RA/QA
KLS Martin, L.P
P.O. Box 50249
Jacksonville, Florida 32250-0249

Re: K050051
Trade/Device Name: Armand Endoscope Holder
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: April 22, 2005
Received: April 25, 2005

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K050051

Device Name: Armand Endoscope Holder

Indications for Use:

The Armand Endoscope Holder is intended for use by surgeons to hold rigid and flexible endoscopes from 14.6mm to 15.8mm in diameter during diagnostic and therapeutic procedures.

Prescription Use __X__ AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE AS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050051